



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0490]

Agency Information Collection Activities; Proposed Collection; Comment Request; Cosmetic Labeling Regulations and Voluntary Cosmetic Registration Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions in FDA's cosmetic labeling regulations and its Voluntary Cosmetic Registration Program (VCRP).

DATES: Submit either electronic or written comments on the collection of information by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The <https://www.regulations.gov> electronic filing system will accept comments

until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2008-N-0490 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Cosmetic Labeling Regulations and Voluntary Cosmetic Registration Program." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover

sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before

submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Cosmetic Labeling Regulations--21 CFR Part 701 and Voluntary Cosmetic Registration

Program--21 CFR Parts 710 and 720

OMB Control Number 0910-0599--Revision

The Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (the FPLA) require that cosmetic manufacturers, packers, and distributors disclose information about themselves or their products on the labels or labeling of their products.

Sections 201, 301, 502, 601, 602, 603, 701, and 704 of the FD&C Act (21 U.S.C. 321, 352, 361, 362, 363, 371, and 374) and sections 4 and 5 of the FPLA (15 U.S.C. 1453 and 1454) provide authority to FDA to regulate the labeling of cosmetic products. Failure to comply with the requirements for cosmetic labeling may render a cosmetic adulterated under section 601 of the FD&C Act or misbranded under section 602 of the FD&C Act.

Cosmetic Labeling Regulations

FDA's cosmetic labeling regulations are codified in part 701 (21 CFR part 701). Section 701.3 requires the label of a cosmetic product to bear a declaration of the ingredients in descending order of predominance. Section 701.11 requires the principal display panel of a cosmetic product to bear a statement of the identity of the product. Section 701.12 requires the label of a cosmetic product to specify the name and place of business of the manufacturer, packer, or distributor. Section 701.13 requires the label of a cosmetic product to declare the net quantity of contents of the product. The information collection provisions found in part 701 are currently approved under OMB control number 0910-0027. To improve the efficiency of Agency operations, we are consolidating these information collection elements into OMB control number 0910-0599.

Voluntary Cosmetic Registration Program

Information collection associated with our VCRP are found in parts 710 and 720 (21 CFR parts 710 and 720). Participants have the option of submitting information via paper forms or via an online interface. The use of the term "form" refers to both the paper form and the online system.

Pursuant to part 710, we request that establishments that manufacture or package cosmetic products voluntarily register with us using Form FDA 2511 entitled "Registration of Cosmetic Product Establishment." The online version of Form FDA 2511 is available on our VCRP website at <https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program/online-registration-voluntary-cosmetic-registration-program-vcrp>. We encourage online registration of Form FDA 2511 because it is faster and more efficient for the filer and the Agency. A registering facility will receive confirmation of online registration, including a

registration number by email. The online system also allows for amendments to past submissions.

Because registration of cosmetic product establishments is not mandatory, voluntary registration provides FDA with the best information available about the locations, business trade names, and types of activity (manufacturing or packaging) of cosmetic product establishments. We store the registration information in a computer database and use the information to generate mailing lists for distributing regulatory information and for inviting firms to participate in workshops on topics in which they may be interested. Registration is permanent, although we request that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

Pursuant to part 720, we request firms that manufacture, pack, or distribute cosmetics to file with the Agency an ingredient statement for each of their products. Filing of cosmetic product ingredient statements is also voluntary. Ingredient statements for new submissions are reported on Form FDA 2512, "Cosmetic Product Ingredient Statement," and on Form FDA 2512a, a continuation form. Amendments to product formulations also are reported on Forms FDA 2512 and FDA 2512a. When a firm discontinues the commercial distribution of a cosmetic, we request that the firm notify FDA that they have discontinued a cosmetic product formulation by submitting an amended Form FDA 2512. If any of the information submitted on these forms is confidential, the firm may submit a request for confidentiality of a cosmetic ingredient.

FDA's use of an electronic submission system has been designed to make it easier for participants to provide information to FDA about their products. The online version of Forms FDA 2512 and FDA 2512a are available on our VCRP website at

<https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program/online-registration-voluntary-cosmetic-registration-program-vcrp>.

Description of Respondents: Respondents to this collection of information include cosmetic manufacturers, packers, and distributors. Respondents are from the private sector (for-profit businesses).

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden¹

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
701.3; ingredients in order of predominance	1,518	21	31,878	1	31,878
701.11; statement of identity	1,518	24	36,432	1	36,432
701.12; name and place of business	1,518	24	36,432	1	36,432
701.13; net quantity of contents	1,518	24	36,432	1	36,432
Total					141,174

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated annual third-party disclosure burden is based on data available to the Agency, our knowledge of and experience with cosmetics, and communications with industry. The hour burden is the additional or incremental time that establishments need to design and print labeling that includes the following required elements: a declaration of ingredients in decreasing order of predominance, a statement of the identity of the product, a specification of the name and place of business of the establishment, and a declaration of the net quantity of contents. These requirements increase the time establishments needed to design labels because they increase the number of label elements that establishments must consider when designing labels. These requirements do not generate any recurring burden per label because establishments must already print and affix labels to cosmetic products as part of normal business practices. We estimate that the total third-party disclosure burden is 141,174 hours.

Table 2.--Estimated Annual Reporting Burden¹

21 CFR Section or Part	Form FDA No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Part 710 (registrations)	2511 ²	1,702	1	1,702	0.20 (12 minutes)	340
720.1 through 720.4 (new submissions)	2512 ³	6,843	1	6,843	0.33 (20 minutes)	2,258
720.6 (amendments)	2512	2,477	1	2,477	0.17 (10 minutes)	421
720.6 (notices of discontinuance)	2512	232	1	232	0.10 (6 minutes)	23
720.8 (requests for confidentiality)		1	1	1	2	2
Total						3,044

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² The term "Form FDA 2511" refers to both the paper Form FDA 2511 and online Form FDA 2511 in the online system known as the VCRP, which is available at <https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program/online-registration-voluntary-cosmetic-registration-program-vcprp>.

³ The term "Form FDA 2512" refers to the paper Forms FDA 2512 and 2512a and online Form FDA 2512 in the online system known as the VCRP, which is available at <https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program/online-registration-voluntary-cosmetic-registration-program-vcprp>.

We base our estimate on information from cosmetic industry personnel and FDA experience entering data submitted on paper Forms FDA 2511, 2512, and 2512a into the online system. We estimate that, annually, 1,702 establishments that manufacture or package cosmetic products will each submit 1 registration on Form FDA 2511, for a total of 1,702 annual responses. Each submission is estimated to take about 0.20 hour per response for a total of 340.4 hours, rounded to 340. We estimate that, annually, firms that manufacture, pack, or distribute cosmetics will file 6,843 ingredient statements for new submissions on Forms FDA 2512 and FDA 2512a. Each submission is estimated to take about 0.33 hour per response for a total of 2,258.19 hours, rounded to 2,258. We estimate that, annually, firms that manufacture, pack, or distribute cosmetics will file 2,477, amendments to product formulations on Forms FDA 2512 and FDA 2512a. Each submission is estimated to take about 0.17 hour per response for a total of 421.09 hours, rounded to 421. We estimate that, annually, firms that manufacture, pack, or distribute cosmetics will file 232 notices of discontinuance on Form FDA 2512. Each submission is estimated to take about 0.10 hour per response for a total of 23.2 hours, rounded to

23. We estimate that, annually, one firm will file one request for confidentiality. Each such request is estimated to take 2 hours to prepare for a total of 2 hours. Thus, the estimated total reporting burden is 3,044 hours.

Our estimated burden for the information collection reflects an overall increase of 3,044 hours and a corresponding increase of 11,255 responses. We attribute this adjustment to an increase in the number of hours and responses due to the consolidation of OMB control numbers 0910-0027 and 0910-0599. Total burden for the combined collection of information is therefore, 144,218 hours (141,174 hours from OMB control number 0910-0599 and 3,044 hours from OMB control number 0910-0027).

Dated: March 30, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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